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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/652,753	08/31/2000	Sonti Venkata Ramakrishna	U 012932-5	3517

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/30/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/652,753	RAMAKRISHNA ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 August 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed August 8, 2001 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Therefore, since there is no translation or explanation of relevance, FR 2637611 has not been considered.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "***means***" and "***said***," ***should be avoided***. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 recites the limitations "the preparation", "the assessment", and "the immobilized biosensing granules". There is insufficient antecedent basis for these limitations in the claim. In addition, it is unclear what the active aerobic microbial consortia are separated from. Further, the recitation of immobilizing the consortia using a polymer is vague and indefinite because the way in which the polymer is used for the immobilization has not been recited, nor has applicant recited on what the consortia is immobilized. Applicant is also advised to change the spelling of "immobilized" or "immobilizing" wherever they appear in any of the claims to conform to American spelling.

6. Claims 2-19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are the way in which the dependent claims, which further limit the steps of parent claim 1, are related to the steps of the parent claim. For example, claim 2 recites various limitations on the process of claim 1. However, applicant has not identified in what way these further limitations are related to the general process recited in claim 1. Where in the process of claim 1 do the steps of claim 2 occur? The sequence of steps of the process, as well as what step of the process is intended to be further limited by each of the dependent claims, has not been identified. Applicant should include language in the dependent claims such as "Process according to claim 1, wherein the immobilization step further comprises..." With such language, the relationship between the dependent claim limitations and the parent claim is clear.

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In addition, it is unclear which part of the process is being limited further with the additional limitations.

7. Claim 2 recites the limitations "the appropriate rpm" in step v, "said biosensing beads" in step vii, "the range" in step ix, and "the activation solution" in step xi. There is insufficient antecedent basis for these limitations in the claim. In addition, in step (iv), applicant should change "condition" to "conditions" and "till" to "until". Further, the recitation of immobilizing the consortia using a polymer is vague and indefinite because the way in which the polymer is used for the immobilization has not been recited, nor has applicant recited on what the consortia is immobilized. The recitations of "known methods" in step vi and "conventional methods" in step xi render the claim vague and indefinite because these terms do not further limit the claim. It is unclear to what applicant is referring with these recitations, thereby rendering the metes and bounds of the claim undefined. Applicant should recite in the claim the methods to which applicant is referring. Claim 2 is also rejected as vague and indefinite for the recitation of dehydrating the beads at a temperature of 24-36 C for 2-20 hours. The temperature and time ranges are broader than the parent claim, thereby rendering the claim improperly dependent. Applicant should also use consistent terminology when referring to the beads or granules. Applicant should use either beads or granules, but not both.

8. The term "appropriate" in claim 2 is a relative term which renders the claim indefinite. The term "appropriate" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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9. The term "several" in claim 2 is a relative term which renders the claim indefinite. The term "several" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

10. Claim 5 recites the limitations "the pH" and "the prepared synthetic growth media". There is insufficient antecedent basis for these limitations in the claim.

11. Claim 6 recites the limitation "the collected microbial consortia". There is insufficient antecedent basis for this limitation in the claim.

12. Claim 7 recites the limitations "the inoculated synthetic growth medium" and "the rate". There is insufficient antecedent basis for these limitations in the claim.

13. Claim 9 recites the limitation "the mixed liquor suspended cells". There is insufficient antecedent basis for this limitation in the claim.

14. Claim 10 recites the limitation "the broth". There is insufficient antecedent basis for this limitation in the claim. The recitation of "conventional methods" is also rejected as vague and indefinite because it is unclear what this term encompasses, thereby rendering the metes and bounds of the claim undefined.

15. Claim 10 is rejected under judicially created doctrine as containing improper Markush language. Applicant is directed to In re Harnsich, 206 USPQ 300. Applicant must amend the claim to read "from the group consisting of ... and ..."

16. Claim 11 is rejected as vague and indefinite because applicant has not recited on what the consortia is immobilized, nor has applicant recited the way in which sodium alginate and calcium chloride are used to facilitate this process.

17. Claim 12 recites the limitation "the range". There is insufficient antecedent basis for this limitation in the claim.

18. Claims 12-15 are rejected as vague and indefinite for the recitation of "immobilized biosensing granules". With the terminology, it is unclear if something is immobilized on the granules or if the granules are immobilized on something else. From prior claims, it doesn't appear that the granules are immobilized on anything.

19. Claim 14 recites the limitations "the calcium chloride solution" and "the aqueous liquid". There is insufficient antecedent basis for these limitations in the claim.

20. Claim 15 is rejected as vague and indefinite for the recitation of dehydrating the beads for 2-20 hours. The time range is broader than the parent claim, thereby rendering the claim improperly dependent.

21. Claim 17 recites the limitations "the activation media" and "the solution". There is insufficient antecedent basis for these limitations in the claim.

22. Claim 18 recites the limitations "the residual dissolved oxygen content", "the effluent", and "the range". There is insufficient antecedent basis for these limitations in the claim. In addition, the recitation of "before and 2-6 hours of addition of activation" is vague and indefinite. It appears that applicant intends to claim that oxygen is measured in the effluent before activation of the granules and 2-6 hours after activation.

23. Claim 19 recites the limitations "the estimation", "the biotreatability", "the dissolved oxygen", and "the activated biosensing granules". Applicant should also correct the spelling of "said".

24. Claim 19 provides for the use of the granules of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Applicant has merely described the classification of the effluent, but has not recited any method steps for estimating biotreatability.

Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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26. Claims 1, 5-6, 8, 10-15, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramakrishna et al. (US Pat. 6,420,146). The reference discloses a process for the preparation of stable yeast crystals. According to the invention, yeast is grown by inoculation in media that was sterilized at 121 degrees Celsius after the pH had been adjusted to 6.8-7.2 using 1 N sodium chloride or 1 N hydrochloric acid. This was then incubated on a shaker at 26-30 degrees Celsius for about 24 hours with aeration. The yeast was then separated by centrifugation at 5,000-15,000 rpm for 10 minutes at 24-32 degrees Celsius. A yeast slurry was then prepared by mixing the yeast 0.5-10% with 0.5-3% natural polymer solution. The immobilized yeast beads were then prepared by adding this solution dropwise into a curing solution of 0.05-0.3 M calcium chloride solution. The beads were kept in this solution overnight at a temperature of 4 degrees Celsius. The immobilized yeast beads were then separated by decanting the solution and washed with distilled water several times. The beads were then dehydrated at a temperature of 24-36 degrees Celsius for 2-20 hours to obtain stable yeast crystals having a moisture content of 5-30%. These crystals were activated by incubation in 5-8% molasses solution for 2-48 hours at 24-32 degrees Celsius. The yeast crystals were then separated by draining this aqueous solution (Col. 4, lines 8-53). Sodium alginate 2% was generally used in preparing the yeast slurry (Col. 4, lines 64).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

30. Claims 4, 7, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (US Pat. 6,420,146).

The reference teaches methods for the preparation of stable yeast crystals, as previously discussed. However, the reference does not teach the specific components of the media, a specific aeration rate, or glucose as the activation solution.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the specific media of the pending claims, as well as an aeration of 5 ml/minute and glucose as activation solution. The selection of these parameters merely represents an optimization of the assay protocol and do not patentably distinguish the claimed

invention over the prior art of record. One of skill in the art would easily be capable of selecting parameters, such as media and aeration rate that promote yeast growth. In addition, one could have also substituted glucose solution for the molasses solution of the reference with a reasonable expectation that the same intended result would be achieved.

31. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (US Pat. 6,420,146) as applied to claims 1, 5-6, 8, 10-15, and 17-19 above, and further in view of Yuan (US Pat. 6,153,416).

Ramakrishna et al. teach methods for the preparation of stable yeast crystals, as previously discussed. However, the reference does not teach selecting a culture from activated sludge.

Yuan teaches the immobilization of microbial cells in polymeric beads. The process of the reference can be used effectively to immobilize yeast, as well as activated sludge microorganisms and waste water treatment microorganisms (Col. 2, line 63 – Col. 3, line 5).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the microbial consortia obtained from wastewater treatment plants as taught by Yuan with the method of Ramakrishna et al. because Yuan teaches that both yeast and waste water microorganisms can be used for immobilization onto beads. Therefore, one could have substituted wastewater microorganisms for the yeast in Ramakrishna et al. with a reasonable expectation of success.

32. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (US Pat. 6,420,146) as applied to claims 1, 5-6, 8, 10-15, and 17-19 above, and further in view of Husain et al. (US Pat. 6,361,695).

Ramakrishna et al. teach methods for the preparation of stable yeast crystals, as previously discussed. However, the reference does not teach the termination of growth at an MLSS of 14,500-15,500 mg/liter.

Husain et al. teach a wastewater treatment system wherein when the MLSS reaches levels of 15 g/l (15,000 mg/liter), some of the mixed liquor is removed from the bioreactor. The MLSS levels must be below this level for effective effluent treatment.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the MLSS levels of Husain et al. with the method of Ramakrishna et al. because after an MLSS of 15,000 mg/liter has been reached, optimal conditions for effluent treatment and growth of microbes no longer exist.

Double Patenting

33. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

34. Claims 1, 4-8, and 10-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146. Although the conflicting claims are not identical, they are not patentably distinct from each other because the steps involved in the methods of the two sets of claims are very similar in scope, thus rendering the claims not patentably distinct. For detailed reasons of the similarities between the sets of claims, applicant is directed to the rejections over Ramakrishna et al. under 35 USC 102 and 35 USC 103. Although these rejections do not specifically address the claims in the '146 patent, the claims closely resemble the part of the disclosure applied in the rejections.

35. Claims 2-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan (US Pat. 6,153,416). The '146 patent teaches the basic method of the claimed invention, but fails to teach the selection of microbial consortia from wastewater treatment plants or activated sludge, a deficiency that is remedied by Yuan, as discussed under 35 USC 103.

36. Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Husain et al. (US Pat. 6,361,695). The '146 patent teaches the basic method of the claimed invention, but fails to teach the specific range of MLSS of the claimed invention, a deficiency that is remedied by Husain et al., as discussed under 35 USC 103.

Conclusion

Claims 1-19 are rejected.

References: Razavi-Shirazi, Harder et al., Neyra et al., Joung et al., and Ramakrishna et al. (Curr. Sci.) are cited as art of interest for teaching methods for wastewater treatment and/or the immobilization of microbes on particles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

*** *KP*
July 24, 2002

Long
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07/26/02